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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,118	06/20/2003	William W. Cimino	40206.19US01	9143

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
08/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,118	CIMINO, WILLIAM W.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock et al (US 549672) in view of Ruiz et al (US 4650464) in view of Wheeldon et al (US4670007).

1. Maddock discloses a device and method for filling mammary prostheses and tissue expanders. The system rapidly delivers and monitors the delivery of a desired volume of sterile fluid to an implantable device (col. 2, lines 49-58) and comprises a container of sterile fluid 20, a pump 58, and a sterile tubing set 24. Maddock discloses that the tubing set may be made of PVC (col. 7, lines 3-4).

2. Maddock discloses that the device delivers fluid from the container through sterile tubing and to the implant. Therefore the steps of connecting the sterile tubing set and making the end of the tube available for delivery of the fluid by the pump to the surgery site are inherently disclosed.

3. Maddock does not disclose the speed of the pump. However, it is well known in the art that peristaltic pumps such as the one disclosed by Maddock are capable of delivering fluid at virtually any rate. Maddock also does not explicitly disclose the volume of fluid delivered. Maddock discloses that the device is capable of rapidly filling a breast implant, and applicant discloses that for filling breast implants, volumes of interest are typically from 100-500ml (p.5,

lines 18-19 of specification). Therefore, it would have been obvious that the volume delivered would be the volume known to be typical for breast implants.

3. Regarding claim 1, Maddock discloses that the volume of fluid delivered can be determined using indicia on the fluid container (col. 5, lines 5-15, see Fig. 4) but fails to disclose a strain gauge sensor, a processor for processing the electric output form the strain gauge sensor, or a display for displaying the amount of fluid delivered during the procedure. Ruiz teaches a method of monitoring infusion of fluid to a patient by monitoring the decreasing weight of the fluid receptacle using a weight sensing transducer 12, wherein a processor processes the electrical output from the sensor from time to time to determine the volume of fluid delivered which is then displayed on a display terminal 24 (col. 2, lines 22-55). Ruiz discloses that such a weight sensing transducer is beneficial over determining the volume delivered by visual inspection of indicia on the fluid container as is previously used in the art because it is more accurate and less labor intensive and decreases the chances of human error (col. 1, lines 15-43). The processor is used only to determine the volume of fluid delivered and is not coupled to any other components of the infusion system. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock to include a weight sensing transducer and the corresponding processor and display as taught by Ruiz because such a transducer is a much more reliable and accurate method of monitoring the amount of fluid delivered to the patient than visually inspecting volume indicia on the fluid container.

4. Ruiz teaches a weight sensing transducer but fails to explicitly disclose that the sensor is a strain gauge. Wheeldon teaches that a strain gauge is a known type of weight sensing transducer that is commonly used in the medical field and has the performance characteristics

that meet the requirements for use with a medical fluid delivery system (col. 4, lines 35-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock in view of Ruiz to include a weight sensing transducer that is a strain gauge as taught by Wheeldon because a strain gauge is a known type of weight sensing transducer that is appropriate for use in a medical fluid delivery system.

5. Regarding claim 10, Maddock discloses the method as described above but fails to disclose a the step of supporting the fluid from a strain gauge sensor, or processing the electric output form the strain gauge sensor. Ruiz teaches a method of monitoring infusion of fluid to a patient by monitoring the decreasing weight of the fluid receptacle using a weight sensing transducer 12, wherein a processor processes the electrical output from the sensor from time to time to determine the volume of fluid delivered (col. 2, lines 22-55). The fluid container hangs from the weight sensing transducer. Ruiz discloses that such a weight sensing transducer is beneficial over determining the volume delivered by visual inspection of indicia on the fluid container as is previously used in the art because it is more accurate and less labor intensive and decreases the chances of human error (col. 1, lines 15-43). The processor is used only to determine the volume of fluid delivered and is not coupled to any other components of the infusion system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock to include a weight sensing transducer and the corresponding processor and display as taught by Ruiz because such a transducer is a much more reliable and accurate method of monitoring the amount of fluid delivered to the patient than visually inspecting volume indicia on the fluid container.

6. Ruiz teaches a weight sensing transducer but fails to explicitly disclose that the sensor is a strain gauge. Wheeldon teaches that a strain gauge is a known type of weight sensing transducer that is commonly used in the medical field and has the performance characteristics that meet the requirements for use with a medical fluid delivery system (col. 4, lines 35-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock in view of Ruiz to include a weight sensing transducer that is a strain gauge as taught by Wheeldon because a strain gauge is a known type of weight sensing transducer that is appropriate for use in a medical fluid delivery system.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock in view of Ruiz in view of Wheeldon as applied to claim 1 above, and further in view of Savage et al (US 6319221). Maddock, Ruiz and Wheeldon are silent as to a reset button. Savage teaches a weighing system that includes a reset button that will zero the display to allow the user to reset the system and monitor the changes in weight in a new time period (col. 8, lines 1-15). This feature is beneficial in a system such as the one disclosed by Maddock were the pump will be used to fill two breast implants. The volume of fluid delivered to the first implant can be measured, the display reset and the volume delivered to the second implant can be measured.

Response to Arguments

8. Applicant's arguments filed 6/7/10 have been fully considered but they are not persuasive. Applicant argues that the number of rejections issued by the Office speaks to the non-obviousness of the instant invention. This is not the case as is evidenced by the rejection above.

9. Applicant argues that Maddock does not describe the use of a processor for processing the electrical output form the strain gauge sensor from time to time to determine the volume of fluid delivered in the procedure. The examiner agrees. This deficiency is remedied by Ruiz and Wheeldon.

10. Applicant argues that Wheeldon does not provide for a processor that does not adjust the speed of the pump at any time. The examiner agrees with this assertion as well. However, Ruiz teaches a processor whose only function is to process electrical output from a weight sensing transducer and display the weight or volume of the fluid that has been delivered to the patient. This weight sensing transducer is used in place of the volume measuring procedure of Maddock which includes viewing the amount of fluid that has left the container using the volume index on the fluid container. Wheeldon is only being relied upon to teach that a strain gauge is a known weight sensing transducer. The processor of Wheeldon and the associated pump controlling functions are not part of the instant rejection.

11. Applicant argues that Maddock does not inherently deliver fluid at the claimed rate. This is not an inherency rejection. The limitation "the pump having speed control adjustable by a user *for delivery of the sterile fluid at a rate...*" is considered to be an intended use limitation. To meet the claim limitation the prior art need only be capable of performing the claimed function. Maddock discloses that the device is used in the same procedure as the claimed invention and therefore it is capable of performing the claimed function. Applicant has failed to disclose anything particular about the claimed peristaltic pump that would have it perform differently than any other peristaltic pump in the prior art.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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